



Paul E. Helliker
Director

Department of Pesticide Regulation



Gray Davis
Governor
Winston H. Hickox
Secretary, California
Environmental
Protection Agency

DEPARTMENT OF PESTICIDE REGULATION PESTICIDE REGISTRATION AND EVALUATION COMMITTEE Meeting Minutes – September 20, 2002

Committee Members/Alternates in Attendance:

Claudia Moore, Integrated Waste Management Board (IWMB)
Syed Ali, State Water Resources Control Board (SWRCB)
Barry Wilson, Department of Environmental Toxicology, University of California-Davis (UCD)
Kathleen Thuner, San Diego County Department of Agriculture
Rupali Das, Department of Health Services (DHS)
Barbara Todd, Department of Food and Agriculture (CDFA)
Lynn Baker, Air Resources Board (ARB)
Tobi Jones, Department of Pesticide Regulation (DPR)
Anna Fan, Office of Environmental Health Hazard Assessment (OEHHA)

Visitors in Attendance:

Joe Frank, DPR
Andre de Fontaine, Cal EPA
John Pearson, Compliance Service
Joyce Wilson, UCD
Jim Goodbrod, DPR
Arthur Lawyer, Technology Science Group, Inc.
David Gihof, Environmental Micro Analysis
Eileen Mahoney, DPR
David Haskell, DPR
Derek Gammon, DPR
Randy Segawa, DPR
Chuck Andrews, DPR
Jon Shelgren, DPR
Rich Bireley, DPR

1. Introductions and Committee Business – Tobi Jones, Chairperson

- a. About 23 people attended the meeting.
- b. Several corrections were made to the minutes of the previous meeting held on July 19, 2002.

FLEX YOUR POWER! The energy challenge facing California is real. Every Californian needs to take immediate action to reduce energy consumption. For a list of simple ways you can reduce demand and cut your energy costs, see our Web site at <www.cdpr.ca.gov>.



2. Status of Regulations on Pesticide Exposure Studies Involving Human Participants–
Joe Frank, DPR

Joe's presentation was designed to introduce participants to recent modifications to the regulation pertaining to pesticide safety studies involving human participants (Title 3 California Code of Regulations Section 6710).

Before a pesticide can be sold or used in California, it has to be evaluated and registered by DPR. Pesticide manufacturers (registrants) must submit studies that document the potential health and environmental effects of their products. DPR often requires that registrants submit human exposure data to satisfy certain pesticide registration or regulatory requirements. In addition, DPR scientists conduct field studies each year to monitor worker exposure to pesticides. These studies help develop better methods to evaluate exposure and to prevent overexposure. Pesticide exposure studies are necessary in order to provide reliable and accurate exposure estimates for risk assessment. Using human participants enables researchers to obtain more relevant data regarding human health effects than could be obtained from animal studies. Because of the wide variety of climatic conditions and the diversity of crops grown in California, researchers can conduct a wide variety of human exposure studies within the state.

Section 6710 states that no person shall conduct any pesticide exposure study in California, which involves human participants, unless the Director of DPR has given written approval of the study protocol. The regulation mandated that DPR submit protocols to an appropriate human subjects review committee of a public or private California research university, which had an agreement with DPR to review such protocols. The committee then made a recommendation to DPR regarding approval of the protocol.

Previously, DPR contracted with the University of California at San Francisco (UCSF) to have its Committee on Human Research (CHR) review protocols for studies to be conducted by DPR's Worker Health and Safety Branch scientists. The CHR also reviewed protocols submitted to DPR by pesticide registrants, task forces, consultants, and others. In 2001, UCSF discontinued its agreement with DPR. Following this termination of the agreement, DPR was unable to find another public or private California university to review the protocols. Since the text of section 6710 was based upon the guidelines and requirements of the CHR, it has been necessary for DPR to completely revise it to provide an alternative means of ensuring appropriate ethical review of the protocols.

The emergency and proposed permanent regulations would require a study director to contract with an Institutional Review Board (IRB) to conduct the ethical review of a protocol involving a California pesticide study using human participants. The study director would be required to submit all protocols directly to the IRB. DPR would accept an IRB's review provided it meets the requirements as specified in Title 40, Code of Federal Regulations, Protection of Environment, Part 26, Protection of Human Subjects, and provides adequate protection to the participants.

3. Director's Proposed Decision on Methyl Isothiocyanate (MITC)-Generating Compounds as Toxic Air Contaminants Randy Segawa, DPR

Randy informed everyone that DPR received the Scientific Review Panel's (SRP) findings on MITC on August 14, 2002. The SRP found that DPR's health evaluation was based on sound science. The margins of exposure for acute exposure ranged from <1 to 17, based on human toxicology data. The margins of exposure for seasonal exposure ranged from 1 –50 based on animal toxicology data. The SRP recommended listing of metam sodium, metam potassium, dazomet, MITC, and other breakdown products of metam sodium.

DPR must adhere to certain legal requirements for listing pesticides as toxic air contaminants (TACs). TACs are defined by law and regulation as pesticides; breakdown products are not included in this definition. DPR must issue a proposed decision within 10 days of receiving the SRP findings. DPR lists if the margin of exposure is less than 10-fold of the level that is adequately protective.

DPR issued its proposed decision on August 24, 2002. MITC meets the criteria for listing. DPR proposed to list MITC and other pesticides that generate MITC as TACs. DPR lacks the legal authority to list breakdown products. DPR will control breakdown products by regulating the parent compounds.

The proposed decision will remain posted until September 27. At that time, DPR will initiate rulemaking to add MITC and other pesticides that generate MITC to the TAC list, according to the following estimated schedule:

October 2002:	Consult with the Department of Food and Agriculture
November 2002:	Notice proposed regulation to list
December 2002:	Public comment period, including hearing
January 2003:	Submit regulation to the Office of Administrative Law (OAL) for review
March 2003:	Regulation adopted, if OAL approves.

DPR plans to implement control measures. Due to the lengthy TAC process, DPR will mitigate using other legal authority.

4. Consultation on Pesticide Impacts on Sierra Nevada Amphibians-Jon Shelgren, Rich Bireley, and Randy Segawa, DPR

Tobi Jones introduced this topic as a consultation with members of the committee as part of DPR's equivalency under the California Environmental Quality Act. Some of the issues raised in received comments are leading-edge scientific issues, and are beyond the scope of DPR's expertise. DPR is seeking advice from the committee on next steps that DPR should take.

Jon Shelgren, Richard Bireley and Randy Segawa presented details of data they reviewed concerning the causes of amphibian declines and deformities in the Sierra Nevada

Mountains. Most of the data were submitted as part of the comments by the Jumping Frog Research Institute, The League to Save Lake Tahoe, Californians for Alternatives to Toxics, and Michael Graf as an individual. DPR staff also reviewed additional papers from the scientific literature. Jon Shelgren discussed the known and suspected causes (and interactions) of frog deformities and mortalities including fatal pathogens and pesticide impacts.

Richard Bireley focused on pesticides and what we knew about their impacts on amphibian populations. There were relatively few papers on the chronic effects of pesticides on amphibians. No direct connections could be discerned from the data implicating pesticides as a significant cause of amphibian declines in the Sierra Nevada.

Randy Segawa detailed the results of air flow monitoring of “upwind agriculture” from the San Joaquin Valley to the Sierra Nevada Mountains, concluding that pesticide applications are a contributing and likely primary source of the detections of pesticide residues in the Sequoia National Park.

There was considerable discussion by committee members and the presenters about the submitted data, further data needs, and approaches to consulting with the scientific community. Brian Finlayson, DFG, indicated that DFG would review the papers and advise DPR.

5. Considerations of Meeting Time– Tobi Jones, DPR

Discussion postponed until the November meeting.

6. Agenda Items for Next Meeting and Location – Tobi Jones, DPR

Claudia Moore, IWMB, requested that data requirements for product registration be discussed.

The next meeting will be held on Friday, November 15, 2002 in the Sierra Hearing Room located on the second floor of the Cal/EPA building.

7. Closing Comments – Tobi Jones, DPR

The meeting was adjourned.